

IN THE CIRCUIT COURT FOR ST LOUIS CITY
MISSOURI STATE COURT



CECIL BRINKER,
individually and on behalf of
all others similarly situated,

Plaintiffs,

v.

THE KRAFT HEINZ FOODS COMPANY,
and DOES 1 through 10,

Defendants.

Case No. _____

JURY TRIAL DEMANDED

PLAINTIFF'S CLASS ACTION COMPLAINT

Plaintiff Cecil Brinker, individually and on behalf of all others similarly situated, hereby files this Class Action Complaint, against The Kraft Heinz Foods Company, and DOES 1 through 10 (collectively "Defendants") for their false, misleading, and deceptive marketing of their products constituting breach of warranty, breach of implied contract, and unjust enrichment, and, in the state of Missouri, violations of the Missouri Merchandising Practices Act, Mo. Rev. Stat. chap. 407 ("MMPA").

1. Defendant markets and sells consumer products, including microwaveable and non-microwaveable Kraft Mac & Cheese products that have packaging which prominently display on the front of the label that the products contain "No Artificial Flavors, Preservatives, or Dyes," but nonetheless contain citric acid – a well-known synthetic preservative in food (collectively, the "Products").¹

¹ "Products" includes all microwaveable and non-microwaveable Kraft Mac & Cheese products labeled as containing "No Artificial Flavors, Preservatives, or Dyes" that include citric acid as an ingredient. The Products include, but are not limited to microwaveable Kraft Mac & Cheese Original Flavor, microwaveable Kraft Mac & Cheese spirals. In addition, the non-microwaveable versions of Kraft Mac & Cheese also bear the false "No preservatives" claims and are included herein as "Products." Those products include Kraft Mac & Cheese Original Flavor, Kraft Mac & Cheese Thick 'n Creamy, and Kraft Mac & Cheese Three Cheese.

2. Because of the presence of citric acid which functions as a preservative in the Products, the claim “No Artificial Flavors, Preservatives, or Dyes,” is false.

3. An example of the Products’ packaging, prominently stating the “No Artificial Flavors, Preservatives, or Dyes” false claim, is depicted below:



4. Although prominently claiming that the Products contain “No Artificial Flavors,

Preservatives, or Dyes,” the fine-print ingredients reveal that the Products all contain citric acid, which (unbeknownst to the reasonable consumer) is a well-known synthetic preservative used in food products.

5. Nonetheless, despite the Products containing the known preservative citric acid, Defendants’ claim they have “No Preservatives” to appeal to consumers who expect a premium product free from preservatives.

6. For all these reasons – and those set forth further below – representing that the Product has “No Artificial Flavors, Preservatives, or Dyes” is false, misleading and deceptive.

7. Pursuant to the MMPA, such practice is illegal.

8. In addition, and/or in the alternative to the above, since the initial offering of the Products, each and every container of the Products has borne a uniformly-worded label falsely claiming the Products contain “No Artificial Flavors, Preservatives, or Dyes.” That uniformly-worded false statement gives rise to additional and/or alternative claims under Missouri law.

I. PARTIES, JURISDICTION, AND VENUE

9. Plaintiff Cecil Brinker is a citizen and resident of St. Louis, Missouri.

10. Plaintiff brings this Class Action Complaint individually and on behalf of a putative class of Missouri residents, and/or a putative subclass of consumers from certain states, the “Consumer Protection Subclass.”

11. Defendant The Kraft Heinz Foods Company (“Kraft”) is a Delaware corporation having its principal place of business at One PPG Place, Pittsburgh, Pennsylvania, 15222. Kraft may be served through its registered agent located at CT Corporation System, 120 S. Central Ave., Clayton, MO 63105.

12. The true names and capacities of the Defendants sued herein as DOES 1 through 10, inclusive, are currently unknown to Plaintiff, who therefore sues such Defendants by fictitious names. Each of the Defendants designated herein as a DOE is legally responsible for the unlawful acts alleged

herein. If necessary, Plaintiff will seek leave of Court to amend the Petition to reflect the true names and capacities of the DOE Defendants when such identities become known.

13. Defendants, directly and through their agents, have substantial contacts with, and receive substantial benefits and income from and through the State of Missouri. Defendants are the owners, manufacturers, and distributors of the Products, and the entities that created and/or authorized the false, misleading, and deceptive packaging of the Products.

14. Venue is proper in this Court because Plaintiff was injured in this venue and lives within this venue.

15. This asserted class action comports with Missouri Supreme Court Rule 52.08 and with R.S.Mo. § 407.025(3) of the MMPA. Plaintiffs' identities can be ascertained from Defendant's records, but are so numerous that simple joinder of all individuals is impracticable. This action raises questions of law and fact common among Plaintiffs. The claims of lead Plaintiff is typical of all Plaintiffs' claims. Named Plaintiff will fairly and adequately protect all Plaintiffs' interests, and is represented by attorneys qualified to pursue this action. More specifically:

16. Class definitions: Plaintiff brings this action on behalf of Plaintiff and a class of similarly-situated persons preliminarily-²defined as follows: All persons who purchased the Products³ during the Class Period while in one of the specific states listed *infra* having consumer protection statutes materially-identical to the MMPA ("Consumer Protection States"). In addition, and/or alternatively, Plaintiff brings this action on behalf of herself and a Missouri subclass of similarly-

² Plaintiff reserves the right to propose, as needed, any different or other more- or less-specific class, classes, subclass, or subclasses as Plaintiff deems appropriate for purposes of class certification. Included within this reservation is a potential subclass of those citizens in those states having consumer protection laws materially-similar to the MMPA, set forth *infra*. Each state therein has a consumer protection statute that broadly prohibits deceptive conduct; likewise, no state requires proof of individualized reliance, or proof of Defendant's knowledge or intent. Thus, Defendant's conduct alleged herein violates each statute's shared prohibitions.

³ As that term and label is defined herein.

situated persons defined as follows: All persons, who, within the Class Period, purchased the Products in the State of Missouri. The Class Period begins five years prior to the date of the filing of this Petition, and ceases upon the date of the filing of this Petition. Excluded from the Class and Subclass are: (a) any judges presiding over this action and members of their staffs and families; (b) the Defendants and their subsidiaries, parents, successors, and predecessors; any entity in which the Defendants or their parents have a controlling interest; and the Defendants' current or former officers and directors; (c) employees (i) who have or had a managerial responsibility on behalf of the organization, (ii) whose act or omission in connection with this matter may be imputed to the organization for liability purposes, or (iii) whose statements may constitute an admission on the part of the Defendants; (d) persons who properly execute and file a timely request for exclusion from the class; (e) the attorneys working on the Plaintiffs' claims; (f) the legal representatives, successors, or assigns of any such excluded persons; and (g) any individual who assisted or supported the wrongful acts delineated herein.

17. Numerosity: Upon information and belief, the Class and Subclass includes at least tens-of-thousands of individuals on a multiple-state basis, making their individual joinder impracticable. Although the exact number of Class members and their addresses are presently unknown to Plaintiff, they are ascertainable from Defendants' records.

18. Typicality: Plaintiff's claims are typical of those of the Class because all Plaintiffs were injured by the Defendants' uniform wrongful conduct, specifically, using misleading and deceptive marketing and advertising in offering and selling the Products to Plaintiffs.

19. Adequacy: Plaintiff is an adequate representative of the Class because Plaintiff's interests do not conflict with the interests of the Class members Plaintiff seeks to represent, Plaintiff has retained competent and experienced counsel, and Plaintiff intends to prosecute this action vigorously. The interests of the Class will be protected fairly and adequately by Plaintiff and his counsel.

20. Commonality: Common questions of law and fact exist as to all Class members and

predominate over any questions affecting only individual members, such as: (a) whether the Defendant used deceptive or misleading marketing and advertising in selling the Products; (b) whether and to what extent the Class members were injured by Defendant's illegal conduct; (c) whether the Class members are entitled to compensatory damages; (d) whether the Class members are entitled to declaratory relief; and (e) whether the Class members are entitled to injunctive relief.

21. Superiority: This class action is appropriate for certification because class proceedings are superior to all other available methods for the fair and efficient adjudication of this controversy. The damages suffered by the individual Class members will likely be small relative to the burden and expense of individual prosecution of the complex litigation necessitated by the Defendant's wrongful conduct. Thus, it would be extremely difficult for the individual Class members to obtain effective relief. A class action presents far fewer management difficulties and provides the benefits of a single adjudication, including economies of time, effort, and expense, and uniformity of decisions.

PLAINTIFF'S CLAIMS

22. Because the Products all contain citric acid, a well-known preservative, the Products' "No Artificial Flavors, Preservatives, or Dyes" claim is false, misleading and deceptive, all in violation of the Missouri Merchandising Practice Act, and various other Missouri and similar-state consumer laws.

23. Average and reasonable consumers such as Plaintiff generally do not read the fine print on the rear or side of a package when purchasing the Products. Moreover, although it is well-established scientifically (and in the various other manners set forth *infra*), the reasonable consumer does not recognize citric acid as a preservative.

24. Plaintiff and other consumers purchased the Products due to their belief that the Products have "No Artificial Flavors, Preservatives, or Dyes."

25. Indeed, as shown *supra*, that statement is prominently advertised on the Products'

packaging:



26. Plaintiff and the Class made their purchasing decisions in reliance upon Defendant's advertised claims that the Products contain "No Artificial Flavors, Preservatives, or Dyes."

27. Plaintiff and the Class reasonably and detrimentally relied upon the Products' front labels in this respect.

28. This is especially true in light of the fact that the average consumer spends less than 20 seconds making any individual in-store purchasing decision.⁴ Indeed, most consumers shop in a relatively hurried fashion, and cannot stop to closely analyze every single product to decipher every deception.⁵

29. Under these circumstances, the prominent, attention-grabbing "front-of-the-box" claim

⁴ Randall Beard, *Make the Most of Your Brand's 20-Second Window*, NIELSEN (Jan. 13, 2015), <https://www.nielsen.com/us/en/insights/article/2015/make-the-most-of-your-brands-20-second-window/> (citing *Shopping Takes Only Seconds... In-Store and Online*, EHRENBURG-BASS INSTITUTE OF MARKETING SCIENCE (2015)) (last visited May 14, 2023).

⁵ See, e.g., *Bell v. Publix Super Markets, Inc.*, 982 F.3d 468, 481 (7th Cir. 2020) (stressing that reasonable consumers, in purchasing "everyday" items such as "low-cost groceries," are likely to exhibit a low degree of care); *Danone, US, LLC v. Chobani, LLC*, 362 F. Supp. 3d 109, 123 (S.D.N.Y. 2019) ("[A] parent walking down the dairy aisle in a grocery store, possibly with a child or two in tow, is not likely to study with great diligence the contents of a complicated product package, searching for and making sense of fine-print disclosures Nor does the law expect this of the reasonable consumer.").

that the Product contains “No Artificial Flavors, Preservatives, or Dyes” is the only thing noticed by a harried consumer rushing through their shopping routine. Plaintiff and the Class would not have purchased the Products had they known that the Products’ claim of “No Artificial Flavors, Preservatives, or Dyes,” was in fact false. Unfortunately, however, buried in the fine-print ingredient boxes on the back of each Product is the revelation that the Products all contain citric acid:

Microwaveable “Spirals”:



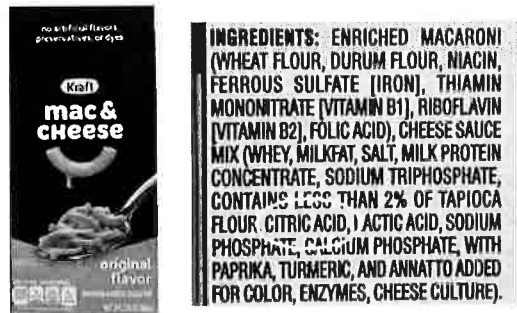
Microwaveable “Original Flavor”:



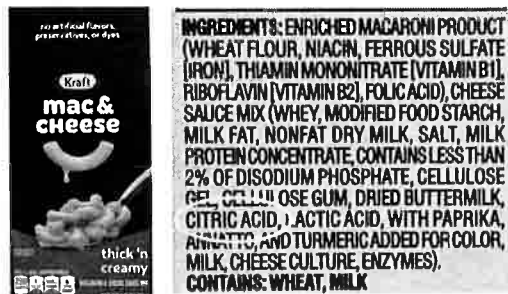
“Three cheese”:



“Original flavor”:



“Thick ‘n Creamy”:



30. Citric acid, while non-toxic and permitted as an additive, is indisputably a synthetic preservative, being categorized as such by essentially every single governmental, scientific, and academic institution considering the question.

Citric Acid Is a Synthetic Preservative

31. Citric acid is a synthetic, non-natural ingredient. Commercial food manufacturers, such as Defendant, use a synthetic form of citric acid that is derived from heavy chemical processing.⁶

32. While the chemical's name has the word “citric” in it, citric acid is no longer extracted from the citrus fruit but is industrially manufactured by fermenting certain genetically modified strains of the black mold fungus, *Aspergillus niger*.⁷ Defendant uses synthetic manufactured citric acid in the Products, sourced from *aspergillus niger*.

33. The Food and Drug Administration (“FDA”), which has primary authority to establish labeling requirements for foods and food ingredients under its purview pursuant to the FDCA,⁸ has identified citric acid as being a synthetic ingredient.

⁶ A. Hesham, Y. Mostafa & L. Al-Sharqi, *Optimization of Citric Acid Production by Immobilized Cells of Novel Yeast Isolates*, 48 MYCOBIOLOGY 122, 123 (2020), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7178817/>

⁷ *Id*; Pau Loke Show, *et al.*, *Overview of citric acid production from Aspergillus niger*, FRONTIERS IN LIFE SCIENCE, 8:3, 271-283 (2015), available at <https://www.tandfonline.com/doi/full/10.1080/21553769.2015.1033653> see also, Belen Max, *et. al.*, *Biotechnological Production of Citric Acid*, Brazilian Journal of Microbiology, 41.4 Sao Paolo (Oct./Dec. 2010).

⁸ 21 U.S.C. § 301, *et. seq.*

34. As just one example, the FDA's classification of citric acid as a synthetic ingredient is confirmed by its warning letter, date October 29, 2001, to Hirze Canning Company ("Hirtzel") regarding its canned tomato products. See Exhibit B. Therein, the FDA stated that these products could not bear an "all natural" claim on the label because the products contained a synthetic ingredient, citric acid.

35. Specifically, the letter states, in pertinent part:

[A]ccording to the ingredients statements ... citric acid are added to the products ... FDA's policy regarding the use of "natural" means that nothing artificial or synthetic has been included, or has been added to, a food that would not normally be expected to be in the food. Therefore, *the addition of ... citric acid to these products preclude the use of the term "natural" to describe this product.*"

Exhibit B (emphasis added).

36. Because the Hirzel products contained a synthetic ingredient (citric acid), preventing the products from bearing a "natural" claim, the FDA informed Hirzel that the products were misbranded. In short, the FDA clearly designates citric acid as artificial and synthetic.

37. Similarly, on August 16, 2001, the FDA sent Oak Tree Farm Dairy, Inc. ("Oak Tree"), a warning letter regarding its "Oaktree Real Brewed Ice Tea," and other products. See Exhibit C. With respect to the Ice Tea product, the FDA stated that the product could not bear "100% Natural" and "All Natural" claims on the label because the product contained a synthetic ingredient, citric acid.

38. Specifically, the letter states, in pertinent part:

"[t]he term "all natural" on [a separate product] is inappropriate because the product contains sodium sorbate ... FDA's policy regarding the use of "natural" means that nothing artificial or synthetic has been included, or has been added to, a food that would not normally be expected to be in the food. The same comment applies to the use of the terms "100% Natural" and "All Natural" on the [Ice Tea product] because it contains citric acid.

Exhibit C, (emphasis added).

39. As the above makes clear, the FDA and many other sources have repeatedly recognized citric acid added to food product is synthetic and artificial. So too have countless sources recognized

that it necessarily functions as a preservative.

40. Consumption of manufactured citric acid has been associated with adverse health events like joint pain with swelling and stiffness, muscular and stomach pain, as well as shortness of breath.⁹

41. Citric acid acts as a preservative when added to food products, including the Products at issue. This is true regardless of its intended use. The FDA defines a preservative as “any chemical that, when added to food, tends to prevent or retard deterioration thereof, but does not include common salt, sugars, vinegars, spices, or oils extracted from spices, substances added to food by direct exposure thereof to wood smoke, or chemicals applied for their insecticidal or herbicidal properties.” 21 C.F.R. §101.22(a)(5). The FDA has listed citric acid as a preservative in its “Overview of Food Ingredients, Additives and Colors” as shown below:¹⁰

Types of Ingredients	What They Do	Examples of Uses	Names Found on Product Labels
Preservatives	Prevent food spoilage from bacteria, molds, fungi, or yeast (antimicrobials); slow or prevent changes in color, flavor, or texture and delay rancidity (antioxidants); maintain freshness	Fruit sauces and jellies, beverages, baked goods, cured meats, oils and margarines, cereals, dressings, snack foods, fruits and vegetables	Ascorbic acid, citric acid , sodium benzoate, calcium propionate, sodium erythorbate, sodium nitrite, calcium sorbate, potassium sorbate, BHA, BHT, EDTA, tocopherols (Vitamin E)

42. As shown, under the “What they Do” table heading, the FDA states that preservatives help “prevent food spoilage from bacteria, molds, fungi or yeast (antimicrobials); slow or prevent changes in color, flavor, or texture and delay rancidity (antioxidants); [and] maintain freshness.”

43. Indeed, the FDA warned companies broadly, well over a decade ago, that citric acid is a preservative. This fact has been settled for quite a while. In a 2010 warning letter sent to Chiquita

⁹ Iliana E. Sweis, *et al.*, *Potential role of the common food additive manufactured citric acid in eliciting significant inflammatory reactions contributing to serious disease states: A series of four case reports*, TOXICOL REP. 5:808-812 (2018), available at <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6097542/>

¹⁰ *Overview of Food Ingredients, Additives & Colors*, FOOD AND DRUG ADMINISTRATION, available at <https://web.archive.org/web/20220901032454/http://www.fda.gov/food/food-ingredients-packaging/overview-food-ingredients-additives-colors>

Brands International, Inc. and Fresh Express, Inc., the FDA warned that certain products were misbranded under the Federal Food Drug and Cosmetics Act because they “contain the *chemical preservatives ascorbic acid and citric acid* but their labels fail to declare these *preservatives* with a description of their functions. 21 C.F.R. [§] 101.22” (emphasis added).¹¹

44. Around the same time, in April of 2010, the International Food Information Council (“IFIC”), acting in conjunction with the FDA, issued a public bulletin informing consumers wanting to avoid preservatives to check if the food’s ingredients include the chemical additives of “[a]sorbic acid [and] citric acid,” which the IFIC and FDA designate as a *preservative*.¹²

Types of Ingredients	What They Do	Examples of Uses	Names Found on Product Labels
Preservatives	Prevent food spoilage from bacteria, molds, fungi, or yeast (antimicrobials); slow or prevent changes in color, flavor, or texture and delay rancidity (antioxidants); maintain freshness	Fruit sauces and jellies, beverages, baked goods, cured meats, oils and margarines, cereals, dressings, snack foods, fruits and vegetables	Ascorbic acid, citric acid, sodium benzoate, calcium propionate, sodium erythorbate, potassium sorbate, BHA, BHT, EDTA, tocopherols (Vitamin E)

45. Citric acid has antioxidant and antimicrobial properties. Citric acid acts as an antioxidant via two processes via two processes—inhibiting enzymes and chelating metals. Certain enzymes naturally exist in food products that oxidize and breakdown the food products’ molecules. Citric acid deactivates these enzymes, thereby functioning as a preservative.¹³ Citric acid also chelates metal ions, which stabilizes and preserves food products by bonding certain molecules in food products to centrally located metal atoms.¹⁴

46. The Encyclopedia Britannica also classifies citric acid as a preservative because it has antioxidant properties, as illustrated below:¹⁵

¹¹ See **Exhibit A** attached hereto.

¹² IFIC and FDA, April 2010 Bulletin: “Overview of Food Ingredients, Additives & Colors, at pp. 2-3, available at: <https://www.fda.gov/files/food/published/Food-Ingredients-and-Colors-%28PDF%29.pdf>

¹³ *Id.*

¹⁴ P. Davidson et al., *Chapter 20: Antimicrobial Agents*, in FOOD ADDITIVES, at 592 (A. Larry Branen et al. eds., Marcel Dekker, Inc. 2d ed. 2002).

¹⁵ *Preservatives*, BRITANNICA, available at <https://www.britannica.com/topic/food-additive/Preservatives#ref502211>

Preservatives

Food preservatives are classified into two main groups: antioxidants and antimicrobials. Antioxidants are compounds that delay or prevent the deterioration of foods by oxidative mechanisms. Antimicrobial agents inhibit the growth of spoilage and pathogenic microorganisms in food.

Food preservatives	
chemical agent	mechanism of action
Antioxidants	
ascorbic acid	oxygen scavenger
butylated hydroxyanisole (BHA)	free radical scavenger
butylated hydroxytoluene (BHT)	free radical scavenger
citric acid	enzyme inhibitor/metal chelator

47. In addition to its antioxidant properties, citric acid also has antimicrobial properties and directly inhibits the growth of some bacteria and mold.¹⁶ This is another, independent reason why food scientists classify citric acid as a preservative.¹⁷

48. The Agricultural Marketing Service of the United States Department of Agriculture (“USDA”) has also recognized the use of citric acid as a preservative stating that “Citric acid has a wide variety of uses, some of which can provide preservative functions, primarily though lowering the pH of the food.”¹⁸

49. The USDA’s Food Safety Inspection Service’s “Guideline for Label Approval” states that “[s]ome common chemical preservatives include BHA, BHT, calcium propionate, citric acid, natamycin and sodium propionate.”¹⁹

50. In addition, several academic journals also note the use of citric acid as a preservative.²⁰

¹⁶ L. Su et al., *Study on the Antimicrobial Properties of Citrate-Based Biodegradable Polymers*, FRONTIERS IN BIOENGINEERING AND BIOTECHNOLOGY, 2, 23. <https://doi.org/10.3389/fbioe.2014.0002>

¹⁷ *Citric Acid Compound Summary*, NAT’L CTR. FOR BIOTECHNOLOGY INFO., <https://pubchem.ncbi.nlm.nih.gov/compound/Citric-acid>.

¹⁸ *Citric Acid and Salts*, UNITED STATES DEPARTMENT OF AGRICULTURE, *available at* <https://www.ams.usda.gov/sites/default/files/media/Citric%20Acid%20TR%202015.pdf>.

¹⁹ FSIS Guideline for Label Approval, UNITED STATES DEPARTMENT OF AGRICULTURE, *available at* https://www.fsis.usda.gov/sites/default/files/media_file/documents/FSIS-GD-2023-0001.pdf

²⁰ K. Kirimura, et al., *Citric Acid*, COMPREHENSIVE BIOTECHNOLOGY (SECOND EDITION) (2011), *available*

In fact, “[C]itric acid acts as a preservative in many processed foods; keeping them fresh. It does this by slowing or helping prevent the formation of bacteria, mold, yeast, and fungus.”²¹ “Today, citric acid is one of the most common and widely-used preservatives in the world[.]”²²

Citric Acid Necessarily Functions as a Preservative in the Products

51. It is *not* necessary that the citric acid in the Products function as a preservative for the “no preservative” claim to be false. Nonetheless, the citric acid functions as a preservative in the Products regardless of whether Defendant intended to use citric acid as a preservative or as flavor enhancer.

52. Citric acid functions as a preservative even if it is also added to the Products for some other use. *See* 21 C.F.R. § 101.22(a)(5)(defining preservatives as “any chemical that, when added to food, *tends to prevent or retard deterioration*”)(emphasis added); *see also* Merriam-Webster’s Dictionary (defining “preservative” as “something that preserves or *has the power of preserving*.”)(emphasis added);²³ Oxford English Dictionary (defining “preservative” as “[t]ending to preserve or *capable of preserving*”).²⁴

53. Indeed, subjective intent of citric acid use is irrelevant. Citric acid functions as a preservative in the Products, and this is true regardless of Defendant’s subjective purpose or intent for

at <https://www.sciencedirect.com/science/article/abs/pii/B9780080885049001690?via%3Dihub>; K.M.S. Islam, *Use of citric acid in broiler diets*, WORLD’S POULTRY SCIENCE JOURNAL VOL. 68, ISSUE 1 (Feb. 21, 2012), available at <https://www.cambridge.org/core/journals/world-s-poultry-science-journal/article/abs/use-of-citric-acid-in-broiler-diets/DA15C2C1F90667525BF2414DF3BFF646> (“Citric Acid (CA) is a weak organic acid which is a natural preservative and can add an acidic or sour taste to foods and soft drinks.”).

²¹ *What is citric acid, and what is it used for?*, MEDICAL NEWS TODAY (July 23, 2021), available at <https://www.medicalnewstoday.com/articles/citric-acid>

²² *Citric Acid: One of the Most Important Preservatives in The World*, FBC INDUSTRIES, INC. (Feb. 5 2019), available at <https://fbcindustries.com/citric-acid-one-of-the-most-important-preservatives-in-the-world/>

²³ *Preservative*, MERRIAM-WEBSTER’S DICTIONARY, available at https://www.merriam-webster.com/dictionary/preservative?utm_campaign=sd&utm_medium=serp&utm_source=jso_nld

²⁴ *Preservative*, American Heritage Dictionary, <https://ahdictionary.com/word/search.html?q=preservative>.

adding it to the Products, such as to impart flavor.²⁵

54. In addition to all of the above reasons establishing that citric acid is a preservative, the following points also cement this understanding and show how citric acid necessarily functions as a preservative in the Products. The following points also illustrate why Defendant's purported intended use of citric acid is completely irrelevant. Regardless of intended uses, citric acid *necessarily* and *unavoidably* tends to, has the power to, and is capable of acting as a preservative.

- a. Because citric acid lowers the PH of food, it helps to create an acidic environment that inhibits the growth of microorganisms, thereby acting as a preservative.²⁶
- b. As noted, citric acid also has an antioxidant effect, which prevents oxidation and spoilage of food products, and thereby acts as a preservative in this manner as well.²⁷
- c. Citric acid also promotes antimicrobial activity, such that it also prevents the growth of bacteria, molds, and yeasts in food products, thus acting as a preservative.²⁸
- d. Citric acid also has chelating properties, so that it can bind to metal ions, such

²⁵ *Citric Acid* in KIRK-OTHMER FOOD & FEED TECH., at 262 (John Wiley & Sons, 2007); L. Somogyi, *Chapter 13: Direct Food Additives in Fruit Processing*, in PROCESSING FRUITS: SCI. & TECH., at 302 (D. Barrett et al. eds., CRC Press 2d ed. 2004); M. Abd- Elhady, *Effect of citric acid, calcium lactate and low temperature prefreezing treatment on the quality of frozen strawberry*, 59 ANNALS OF AGRIC. SCIS., 69-75 (2014); J. deMan, *Chapter 11: Additives and Contaminants*, in PRINCIPLES OF FOOD CHEMISTRY, at 438 (AVI Publishing Co., Inc. 3d ed. 1999) ("Acids as food additives serve a dual purpose, as acidulants and as preservatives.").

²⁶ See, e.g., ECHEM.COM "Is Citric Acid a Preservative: A Complete Guide, June 8, 2023, available at <https://www.echemi.com/cms/1416389.html>

²⁷ See, e.g., Medical News Today, "What is citric acid, and what is it used for?", July 23, 2021, available at: <https://www.medicalnewstoday.com/articles/citric-acid>

²⁸ See, e.g., NIH, National Library of Medicine, C. Burel "Impact of pH on citric acid antimicrobial activity against Gram-negative bacteria," Nov. 22, 2022, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7984346/>

as iron and copper, which are involved in catalyzing oxidative reactions that lead to food spoilage. As such, it acts as a preservative in this additional manner.²⁹

- e. Citric acid can also help retain moisture in products, thereby reducing the risk of microbial growth due to water availability – yet one more fashion in which citric acid acts as a preservative.
- f. Citric acid also has a direct affect as a mold inhibitor, making it an effective preservative for this addition reason.³⁰

55. In addition, and perhaps most importantly, while citric acid can also be employed by a manufacturer that intends to impart taste, a greater quantity of citric acid is required to impart taste than to preserve foods.³¹ The preservative effects of this acid may be reduced at lower levels, but it will still be present.

56. Thus, Defendant cannot argue that it includes citric acid in the Products merely to impart taste, because the quantities required to impart taste are more than sufficient to function as a preservative. Even if imparting taste is Defendant's primary intention for including citric acid, that subjective motivation has no bearing on its objective functioning.

57. For all of the above-stated reasons, and more, it is clear that citric acid is a preservative, regardless of what its intended or subjective use is in the Products is claimed to be. Moreover, even if citric acid's function as a preservative in the Product were somehow otherwise negated or counteracted (which is not apparent here), the "No Artificial Flavors, Preservatives, or Dyes" label is nonetheless

²⁹ See, e.g., ScienceDirect, "Rancidity, Impact of particle size and other ingredients on extrude foods and feeds," Mian N. Riaz, 2012, available at: <https://www.sciencedirect.com/topics/agricultural-and-biological-sciences/rancidity>

³⁰ See, e.g., NIH, National Library of Medicine, Musyoka, Joyce, "Effects of acidification and preservatives on microbial growth during storage of orange fleshed sweet potato puree.", June 7, 2018, available at: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6011086/>

³¹ See, e.g., Sweis, Illiani, fn. 9, *supra*.

false.

58. In short, the mere inclusion of citric acid in the Product, regardless of any other excuse or explanation created by Defendant, renders the “No Artificial Flavors, Preservatives, or Dyes” label false.

Reasonable Consumers are Deceived by Defendant’s False Labeling

59. Consumers, like Plaintiff, relied on Defendant’s “No Artificial Flavors Preservatives, or Dyes” labeling statement. The “No Artificial Flavors, Preservatives, or Dyes” statement on the labels of the Products is material to reasonable consumers. “[F]oods bearing ‘free-from’ claims are increasingly relevant to Americans, as they perceive the products as closely tied to health ... 84 percent of American consumers buy free-from foods because they are seeking out more natural or less processed foods. In fact, 43 percent of consumers agree that free-from foods are healthier than foods without a free-from claim, while another three in five believe the fewer ingredients a product has, the healthier it is (59 percent). Among the top claims “free-from” consumers deem most important are trans-fat-free (78 percent) and preservative-free (71 percent).³²

60. According to another study, when consumers were asked to choose a product that was the closest to their understanding of what “natural” means on product labels, on balance, they chose products with “No Preservatives” labels.³³

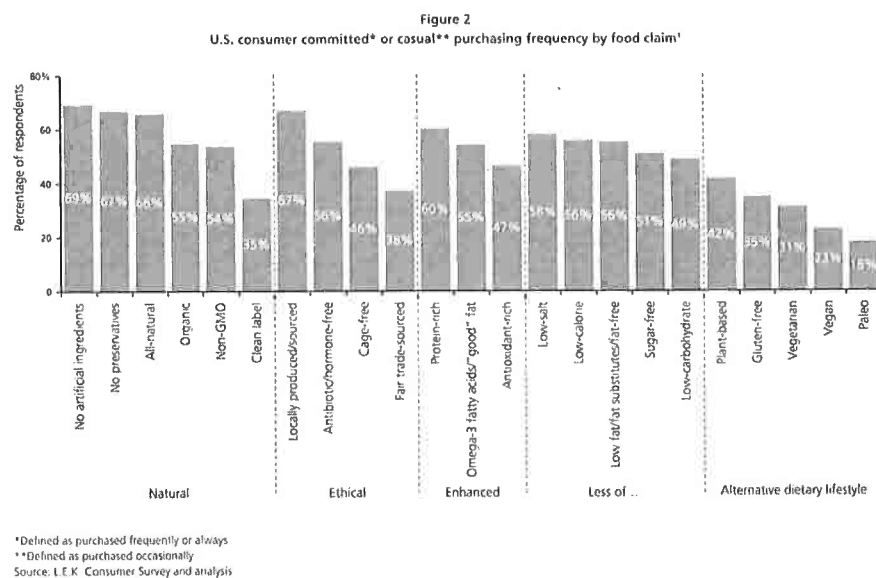
61. In yet another study, the consumers spoke loud and clear in pointing out that a product having “no preservatives” is specifically sought after by a full 67% of consumers, topped *only* by “no artificial ingredients” at 69% (see excerpt below):³⁴

³² 84% of Americans buy “free-from” foods because they believe them to be more natural or less processed, Mintel (Sept. 3, 2015), available at <https://www.mintel.com/press-centre/84-of-americans-buy-free-from-foods-because-they-believe-them-to-be-more-natural-or-less-processed/>

³³ Sajida Rahman, et al., Assessing consumers’ understanding of the term “Natural” on food labeling, *Journal of Food Science*, Vol. 85, No. 6, 1891-1896. (2020).

³⁴ LEK Consulting, Executive Insights; Steingoltz, Maria, et. al., “Consumer Health Claims 3.0: The Next Generation of Mindful Food Consumption,” 2018, available at: <https://www.lek.com/sites/default/files/insights/pdf-attachments/2051-Healthy-Food-Claims.pdf>

Executive Insights



62. Clearly, consumers are overwhelmingly concerned with having “no preservatives,” and strongly prefer healthy food products. *Id.* And this trend is only increasing, as the global sale of healthy food products is estimated to be \$4 trillion dollars and is forecasted to reach \$7 trillion by 2025.³⁵

63. Defendant’s conduct threatens Missouri consumers by using false, deceptive, and misleading labels. Defendant’s conduct also threatens other companies, large and small, who “play by the rules.” Defendant’s conduct stifles competition, has a negative impact on the marketplace, and reduces consumer choice.

64. There is no practical reason for the false or misleading labeling and advertising of the Products, other than to mislead consumers as to the actual nature of the Products, while simultaneously providing Defendant with a financial windfall.

Allegations Relating to All Plaintiffs

65. As noted, *supra*, since the initial offering of the Products, the containers on the front

³⁵ Global Wellness Institute, *The Global Wellness Economy Stands at \$4.4 Trillion Amidst the Disruptions of COVID-19; Is Forecast to Reach \$7 Trillion by 2025*, <https://www.hospitalitynet.org/news/4108643.html>.

packaging of all of the Products has borne one or more uniformly-worded labels falsely claiming the Products contains “No Artificial Flavors, Preservatives, or Dyes” (hereinafter “False Claims”).

66. In reality, for all the reasons set forth *supra*, a reasonable consumer would find that the False Claims are false, misleading, unfair, and/or deceptive.

67. Defendant, as developer, manufacturer, and exclusive seller and distributor of the Products, has been aware since the Products’ inception, that the False Claims are in fact false.

68. Indeed, Defendant undoubtedly did its own investigation of the Products and its marketplace prior to it being offered for sale and, of necessity, such investigation would have made Defendant aware that the False Claims are in fact false.

69. Despite this, Defendants purposely made the False Claims in order to induce the false belief in consumers that they were purchasing a Product that had “No Artificial Flavors, Preservatives, or Dyes.”

70. Plaintiff and the class members purchased the Products without being aware that the Products in fact contain a preservative.

71. Defendant possessed specialized knowledge regarding the data and information concerning the Products and its claims.

72. In purchasing the Products, Plaintiff and the class members had no choice but to necessarily and justifiably rely upon the False Claims as accurate.

73. Had Plaintiff known that the False Claims were false, Plaintiff would not have purchased the Products or would not have paid as much for the Products.

74. If, at some point in the future, the Product was improved to actually have “No Artificial Flavors, Preservatives, or Dyes.” and/or otherwise be accurately labeled, Plaintiffs intend to, and will purchase the Products again.

75. As the direct and proximate result of the False Claims, Plaintiff and the class members

have suffered economic injury by being deprived of the benefit of the bargain they were promised by Defendant.

76. By marketing, selling and distributing the Product to purchasers in Missouri and elsewhere, Defendant made actionable statements that the Products contained “No Artificial Flavors, Preservatives, or Dyes.”

77. Defendant engaged in the above-described actionable statements, omissions and concealments with knowledge that the representations were false and/or misleading, and with the intent that consumers rely upon such concealment, suppression and omissions.

78. Alternatively, Defendant was reckless in not knowing that the False Claims were false and misleading at the time they were made.

79. As the distributor, marketer, producer, manufacturer, and seller of the Products, Defendant possessed specialized knowledge regarding the data and information concerning the amount of Product which the Plaintiff and the class members could not and did not review.

Facts Particular to Named Plaintiff

80. In or around January 21, 2024, Plaintiff purchased one of the non-microwaveable Products from a third-party retailer, Walmart Supercenter, located at 1900 Maplewood Commons Dr., Maplewood, Missouri, 63143.

81. In addition, on or around February 25, 2024, Plaintiff purchased two of the microwaveable Products from a third-party retailer, also the Walmart Supercenter, located at 1900 Maplewood Commons Dr., Maplewood, Missouri, 63143.

82. Due to the claims on the packaging, at each purchase, Plaintiff falsely believed Plaintiff was purchasing a product that contained “No Artificial Flavors, Preservatives, or Dyes.”

83. Plaintiff thereafter purchased the Products. Plaintiff purchased the Product primarily for Plaintiff’s personal, family and household use.

84. At the time Plaintiff purchased the Products, Plaintiff was unaware of the falsity of the Products' claims.

85. Plaintiff discovered that such claims were false only after having purchased and used (ingesting) the Products, which Plaintiff used and prepared properly and according to its instructions in every respect.

86. If Plaintiff had been aware of the falsity and misleading nature of Defendant's claims regarding the Products, Plaintiff would not have bought the Product.

87. When Plaintiff purchased the Products, Plaintiff was injured by Defendant's illegally deceptive, false, and misleading conduct in marketing and selling the Product.

88. Specifically, Plaintiff suffered an ascertainable loss because Plaintiff did not receive the expected benefit of the bargain.

89. When Plaintiff was purchasing the Product, due to the false claims upon the Product, Plaintiff believed that Plaintiff was receiving a product that contained "No Artificial Flavors, Preservatives, or Dyes."

90. The Product was not what it was purported to be. Plaintiff did not receive the value of what Plaintiff bargained for; instead Plaintiff received a product that did not live up to one of its most-prominently advertised benefits – containing no preservatives. Plaintiff did not want a Product with preservatives.

91. Consequently, Plaintiff was damaged in the amount of the difference between the cost paid for the Products as represented – as one that contained "No Artificial Flavors, Preservatives, or Dyes," and the actual value of the Products to consumers seeking products without preservatives.

92. Plaintiff desires to, and will purchase the Products again if they are honestly-labeled in respect to the ingredients within, but faces an imminent threat of harm because Plaintiff will not be able to rely on Defendant's labels in the future (without relief) and will thus be unable to purchase the

Products.

93. Although the aforementioned facts apply to named Plaintiff, for purposes of the proposed Class, all that is relevant is that Plaintiff and the class members purchased the Products at a time within the Class Period while in Missouri and/or one of the Consumer Protection States.

Plaintiffs Claims Are Not Preempted

94. Any claim of “preemption” by Defendant would be misplaced. Plaintiffs’ claims are not preempted by the FDCA because the definition of “preservative,” as used herein, is identical with that of the FDA (see above).

95. Moreover, FDA regulations specifically note that claims like “No Preservatives” are non-nutritive claims that are not governed by 21 C.F.R. §101.13. *See* 21 C.F.R. § 101.65(b)(2).

96. *A fortiori*, since the FDA has never issued specific standards governing when “No Preservative” claims are either true or false, such representations fall outside the ambit of FDA regulations. And even if, *arguendo*, they did not fall outside FDA regulations (which they do), Plaintiff’s claims are *consistent* with FDA regulations.

97. Accordingly, Plaintiffs’ claim cannot possibly be preempted.

CAUSES OF ACTION

COUNTS RELATING TO THE MISSOURI AND CONSUMER PROTECTION SUBCLASSES

COUNT ONE: BREACH OF WARRANTY

98. Plaintiff hereby incorporates by reference and re-alleges each allegation set forth in each preceding paragraph of this Class Action Petition.

99. Defendant sold the Product in its regular course of business. Plaintiff and the class members purchased the Product.

100. Defendant made promises and representations in an express warranty provided to all consumers, namely the False Claims.

101. The False Claims became the basis of the bargain between the Defendant and Plaintiff and each class member.

102. Defendant gave these express warranties to Plaintiff and each class member in written form on the labels of the Product.

103. Defendant's written affirmations of fact, promises, and/or descriptions as alleged are each a written warranty under Missouri law and the laws of the Consumer Protection States.

104. Defendant breached the warranty because the False Claims were false; the Product are not ones that contained "No Artificial Flavors, Preservatives, or Dyes."

105. The False Claims were false when the sales took place and were undiscoverable to Plaintiff and the class members at the time of purchase.

106. All conditions precedent to seeking liability under this claim for breach of express warranty have been performed by or on behalf of Plaintiff and the class in terms of paying for the Product.

107. Defendant had actual notice of the false labeling information and to date has taken no action to remedy its breach of express and implied warranty.

108. Specifically, counsel for Plaintiff mailed a previous copy of this lawsuit to Defendant on March 27, 2024, providing Defendant with written notice of this breach of warranty. In addition, on April 12, 2024, Plaintiff provided Defendant with a copy of this precise lawsuit, including Notice as to the non-microwaveable products. Defendant has not meaningfully responded, and has taken no action to remedy its breach of express and implied warranty.

109. In addition, Defendant previously knew or should have known of the falsity of the False Claims on the Product due to, *inter alia*, Defendant's knowledge of the Product.

110. Defendant has nonetheless refused to remedy such breaches.

111. By placing the Product in the stream of commerce, and by operation of law and the facts

alleged herein, Defendants also impliedly warrantied to Plaintiff and the class members that the Products were accurately labeled in conformance with the law.

112. Defendant's breaches of warranty have caused Plaintiffs and class members to suffer injuries, paying for falsely labeled products, and entering into transactions they otherwise would not have entered into for the consideration paid. As a direct and proximate result of Defendant's breaches of warranty, Plaintiff and class members have suffered damages and continue to suffer damages.

COUNT TWO: BREACH OF IMPLIED CONTRACT UNDER MISSOURI LAW

113. Plaintiff repeats and re-alleges the allegations set forth in the preceding paragraphs as if fully set forth herein.

114. By operation of law, there existed an implied contract for the sale of the Product between Defendant and Plaintiff and each class member who purchased the Product.

115. By operation of Missouri law, there existed an implied duty of good faith and fair dealing in each such contract.

116. By the acts alleged herein, Defendant has violated that duty of good faith and fair dealing, thereby breaching the implied contract between Defendant and each class member.

117. As stated, despite claiming to contain "No Artificial Flavors, Preservatives, or Dyes," the Products all contain citric acid, which is indisputably a preservative.

118. As a result of that breach, Plaintiff and each class member suffered damages.

COUNT THREE: UNJUST ENRICHMENT UNDER MISSOURI LAW

119. Plaintiffs repeat and reallege the allegations set forth in the preceding paragraphs as if fully set forth herein.

120. Plaintiffs plead their claim for relief in the alternative to the contract claims set forth above.

121. Plaintiff and the class members have conferred substantial benefits on Defendant by

purchasing the Product, and Defendant has knowingly and willfully accepted and enjoyed those benefits.

122. By purchasing the Product, Plaintiff conferred a benefit upon Defendant in that Defendant ultimately received funds from the transaction, initially provided by Plaintiff.

123. Upon information and belief, Defendant directly profits from Plaintiff's purchase in such a manner.

124. Accordingly, Defendant was unjustly enriched by Plaintiff and those similarly-situated.

COUNT FOUR: VIOLATION OF THE MMPA & OTHER CONSUMER PROTECTION LAWS

125. Plaintiff hereby incorporates by reference and re-alleges each allegation set forth in each preceding paragraph of this Petition, as though fully set forth herein.

126. Defendant's acts complained of herein occurred in and emanated from the State of Missouri and/or one of the Consumer Protection States.

127. Plaintiff and all members of the Class are "persons" and the Product is "merchandise" as those terms are defined under the MMPA.

128. As set out in this Petition, Defendant's marketing and sale of the Product constitutes deception, false pretense, misrepresentation, unfair practice, or, at a minimum, the concealment, suppression, or omission of a material fact in violation of the Missouri Merchandising Practices Act, Mo. Rev. Stat. chap. 407 ("MMPA"). The statement "No Artificial Flavors, Preservatives, or Dyes," is false, deceptive, and misleading; and Defendant's overall practice is certainly "unfair."

129. As a result of Defendant's actions, consumers, including Plaintiff, were misled or deceived that the Product they were purchasing contained "No Artificial Flavors, Preservatives, or Dyes."

130. In being misled in the manner described herein, Plaintiff was at all times acting as a reasonable consumer would in light of the circumstances.

131. The deceptive practice Defendant engaged in would cause a reasonable person to enter

the transaction described herein, which resulted in damages to Plaintiff.

132. Defendant's deceptive acts caused Plaintiff and the Class Members an ascertainable loss within the meaning of the MMPA. The cost of the Products to consumers can be calculated, and the value of the Products to consumer seeking products without preservatives is nothing. Accordingly, damages can be proven with objective and sufficiently definitive evidence.³⁶

133. Due to Defendant's illegal conduct, Plaintiffs are entitled to restitution of all funds improperly obtained by Defendants.

134. Plaintiffs have been forced to hire attorneys to enforce their rights under the MMPA.

135. For all of the same reasons set forth above, Defendants' conduct also violates the materially-similar consumer protection laws of the Consumer Protection Subclass.

136. Specifically, the following statutes are materially-similar to the MMPA such that they are identically violated by Defendant's conduct as forth herein:

- 1) Alabama Deceptive Trade Practices Act, Ala. Statues Ann. § 8-19-1, *et seq.*;
- 2) Arizona Consumer Fraud Act, Arizona Revised Statutes, § 44-1521, *et seq.*;
- 3) Delaware Deceptive Trade Practices Act, 6 Del. Code § 2511, *et seq.*;
- 4) Georgia Fair Business Practices Act, § 10-1-390 *et seq.*;
- 5) Hawaii Unfair and Deceptive Practices Act, Hawaii Revised Statutes § 480 1, *et seq.*, and Hawaii Uniform Deceptive Trade Practices Act, Hawaii Revised Statutes § 481A-1, *et seq.*;
- 6) Idaho Consumer Protection Act, Idaho Code § 48-601, *et seq.*;
- 7) Kansas Consumer Protection Act, Kan. Stat. Ann § 50 626, *et seq.*;
- 8) Ohio Deceptive Trade Practices Act, Ohio Rev. Code. Ann. § 4165.01. *et seq.*;
- 9) Oklahoma Consumer Protection Act, Okla. Stat. 15 § 751, *et seq.*;
- 10) Tennessee Trade Practices Act, Tennessee Code Annotated § 47-25-101, *et seq.*;
- 11) Virginia Consumer Protection Act, Virginia Code Ann. § 59.1-196, *et seq.*;

("Consumer Protection Statutes")

137. Accordingly, just as the MMPA has been violated by Defendant as alleged herein, each of the above Consumer Protection Statutes, all materially-similar to the MMPA, have also been violated by Defendants.

138. Each of these Statutes is materially similar to the MMPA. Each broadly prohibits

³⁶ Although damages can be calculated readily by a layperson, Plaintiffs also will enlist the aid of appropriate expert witnesses to calculate damages to the utmost precision.

deceptive conduct in connection with the sale of goods to consumers. No state requires proof of individualized reliance, or proof of Defendant's knowledge or intent. Instead, it is sufficient that the deceptive conduct is misleading to reasonable consumers and that the conduct proximately caused harm. Defendant's conduct violates each statute's shared prohibitions.

139. Plaintiff hereby re-incorporates herein the preceding facts that satisfy all of the various elements of each of the Consumer Protection Statutes.

140. Each of the Consumer Protection Statutes prohibits unfair, unconscionable, and/or deceptive acts or practices in the course of trade or commerce or in connection with the sales of goods or services to consumers. Defendant's conduct violates each statute's prohibitions

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray for an order certifying this action as a Consumer Protection Subclass and/or Missouri Subclass class action, and appointing Plaintiff as Class and/or Subclass representative and his counsel as class and/or subclass counsel. Plaintiff requests that this court find that the Defendant is liable pursuant to the aforementioned common law claims; and/or violated the MMPA and/or the Consumer Protection Statutes, and award Plaintiff compensatory damages, restitution, punitive damages, and attorneys' fees, and such further relief as the Court deems just, including injunctive relief.

Respectfully submitted,

DANIEL F. HARVATH, ESQ.

By: /s/ Daniel F. Harvath
Daniel F. Harvath, #57599MO
HARVATH LAW GROUP, LLC
75 W. Lockwood, Suite #1
Webster Groves, MO 63119
(314) 550-3717
dharvath@harvathlawgroup.com
Attorney for Plaintiff

1/23/2015

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Inspections, Compliance, Enforcement, and Criminal Investigations

Fresh Express Incorporated 10/6/10



Department of Health and Human Services

Public Health Service
Food and Drug Administration
San Francisco District
1431 Harbor Bay Parkway
Alameda, CA 94502-7070
Telephone: 510/337-6700

WARNING LETTER**Via UPS**

October 6, 2010

Fernando Aguirre, President and CEO
Chiquita Brands International, Inc. and Fresh Express, Incorporated
250 East Fifth Street
Cincinnati, OR 45202

Dear Mr. Aguirre:

Starting on May 21, 2010 and ending on June 10, 2010, the Food and Drug Administration (FDA) inspected your food manufacturing facility located at 900 E. Blanco Road, Salinas, California. During this inspection, FDA investigators collected labels for your products and reviewed their labeling at

<http://www.chiquita.com>¹. Based on our review, we have concluded that your Chiquita brand "Pineapple Bites with Coconut" and "Pineapple Bites" products are misbranded in violation of the Federal Food, Drug, and Cosmetic Act (the Act) and the applicable regulations in Title 21, Code of Federal Regulations, Part 101 (21 CFR 101). You can find the Act and FDA regulations through links at FDA's Internet home page at <http://www.fda.gov>².

Specifically, your "Pineapple Bites with Coconut" product is misbranded within the meaning of Section 403(a) of the Act [21 U.S.C. § 343(a)] in that its statement of identity, "Pineapple Bites with Coconut", is false and misleading. The ingredient statement for this product states that it is made with coconut; however, our investigation determined that this product is made with a coconut flavor spray. The characterizing flavor of your Pineapple with Coconut product must be identified in accordance with 21 CFR 101.22(i)(1)(iii) (for example, "coconut flavor").

Your "Pineapple Bites" and "Pineapple Bites with Coconut" products are misbranded within the meaning of Section 403(r)(1)(A) of the Act [21 U.S.C. § 343(r)(1)(A)] because their labeling bears nutrient content claims but the products do not meet the requirements for the claims.

Specifically, their labeling includes the claim "Plus ... Antioxidants." However, this claim does not include the names of the nutrients that are the subject of the claim or, alternatively, link the term "antioxidants" by a symbol (e.g., an asterisk) that refers to the same symbol that appears elsewhere on the same panel of the product label, followed by the name or names of the nutrients with recognized antioxidant activity. 21 CFR 101.54(g)(4). Your use of this antioxidant claim therefore misbrands your products under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)].

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Your "Pineapple Bites" and "Pineapple Bites with Coconut" products also bear the claim "Plus Phytonutrients." "Phytonutrients" are not nutrients for which a recommended daily intake (RDI) or daily recommended value (DRV) has been established. Therefore, nutrient content claims regarding "phytonutrients" are not authorized and further misbrand your products under section 403(r)(2)(A)(i) of the Act [21 U.S.C. § 343(r)(2)(A)(i)]. To the extent phytonutrients are intended to be the basis for an antioxidant nutrient content claim, that use would violate FDA regulations for the same reason and because phytonutrients are not recognized as having antioxidant activity. 21 CFR 101.54(g)(1) and (2).

Both your "Pineapple Bites" and "Pineapple Bites with Coconut" products also bear the statement "Only 40 Calories." This statement implies that the products are "low calorie" foods. A "low calorie" claim may be made if a food with a reference amount customarily consumed (RACC) greater than 30 grams (g) or greater than 2 tablespoons does not provide more than 40 calories per RACC. 21 CFR 101.60(b)(2)(i)(A). The RACC established for pineapple is 140 g. See 21 CFR 101.12(b) (Table 2, Fruits and Fruit Juices, All other fruits fresh, canned, or frozen).

The nutrition information for both products states that there are 40 calories per 1 piece (80 g) of product; this equals about 70 calories per RACC. Therefore, under 21 CFR 101.13(i)(2), the products are required to carry a disclaimer adjacent to the claim, e.g., "Only 40 calories per serving, not a low calorie food". Because your products fail to bear the required disclaimer, they are misbranded within the meaning of section 403(r)(1)(A) of the Act.

The "Pineapple Bites" and "Pineapple Bites with Coconut" products are further misbranded within the meaning of section 403(k) of the Act [21 U.S.C. 343(k)] in that they contain the chemical preservatives ascorbic acid and citric acid but their labels fail to declare these preservatives with a description of their functions. 21 CFR 101.22. Further, the ingredients ascorbic acid and citric acid must be declared by their common or usual names. 21 CFR 101.4(a).

This letter is not intended to be an all-inclusive review of your firm's products and processes. It is your responsibility to ensure that your firm and your products comply with the Act and FDA, regulations. You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. For instance, we may take further action to seize your product or enjoin your firm from operating.

We also note that, FDA (through its contractor) obtained two samples of Fresh Express Hearts of Romaine the testing of which yielded human pathogens. One sample was found to contain *Salmonella Anatum*; another sample was found to contain *E. coli O157:H7*. We acknowledge that you issued letters to your customers in an effort to recall affected products. However, FDA recommends that you review your firm's criteria for receipt of raw product, your procedures for ensuring that wash, flume and processing water do not contaminate your products and any other conditions and practices that may relate to the cause of the contamination.

We further acknowledge your June 25, 2010 response to the Good Manufacturing Practices violations cited in the FDA Form 483 regarding this inspection. In your response, you committed to:

- Retrain employees to replace or sanitize their gloves after contacting unsanitized surfaces;
- Include the dryer hoist controls and the equipment control panels that involve direct employee contact in your daily wash and sanitation procedures;
- Create a new storage system for aprons, gloves, and sleeve guards for times during manufacturing when they are not in use; and
- Modify your cutting surface inspection and replacement program so that cutting surfaces will be changed after every (b)(4) of use.

However, you did not provide documentation to demonstrate that these corrections have been made. You also did not address the observation that your technician improperly read the free chlorine indicator tests in the flume water. Please provide this information and documentation in your response to this Warning Letter.

In addition to the labeling issues identified above, we note that the available labeling space is at least 6" in height; therefore, the size of the nutrition information declared on these packages is not appropriate and does not meet the formatting requirements under 21 CFR 101.9(d), including hairline and footnote requirements. We note that since some of the nutrients are at insignificant levels, a shortened version of the Nutrition Facts panel may be used, e.g., the statement "Not a significant source of dietary fiber", at the bottom of the table of nutrient values as allowed under 21 CFR 101.9(c).

Please notify this office in writing within fifteen (15) working days from the date you receive this letter of

1/23/2015

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the specific steps you have taken to correct the noted violations, including an explanation of how you plan to prevent these violations, or similar violations, from occurring again. Please include documentation of the corrective actions you have taken. If your planned corrections will occur over time, please include a timetable for implementation of those corrections. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

Your response should be sent to:

Darlene B. Almogela
 Director of Compliance
 United States Food and Drug Administration
 1431 Harbor Bay Parkway
 Alameda, CA 94502

If you have any questions about the content of this letter please contact Sergio Chavez, Compliance Officer, at 510-337-6886.

/s/

Barbara Cassens
 District Director

Page Last Updated: 10/08/2010

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Inspections, Compliance, Enforcement, and Criminal Investigations

Hirzel Canning Company 29-Aug-01

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
Cincinnati District Office
Central Region
6751 Steger Drive
Cincinnati, OH 45237-3097
Telephone: (513) 679-2700
FAX: (513) 679-2771

August 29, 2001
WARNING LETTER
CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Karl A. Hirzel, President
Hirzel Canning Company
411 Lemoyne Road
Northwood, Ohio 43619

Dear Mr. Hirzel:

During an inspection of your firm on June 13, 2001 our Investigator collected labels for canned tomato products manufactured by your firm. We have limited our review to three of your products, which we have determined to be sufficiently representative of the labeling efficiencies of your products. Our review of the labels collected for the products listed below show that they cause the products to be in violation of Section 403 of the Federal Food Drug, and Cosmetic Act (the Act) and Title 21, Code of Federal Regulations (CFR), Part 101- Food Labeling as follows:

Dei Fratelli CONCENTRATED/ITALIAN STYLE TOMATO PUREE No Salt Added (28 OZ. Cm)

The above product is misbranded within the meaning of Section 403 (a)(1) of the Act in that its labeling is false or misleading. The term "FRESH-PACKED" used on the principal display panel, which falsely implies that the finished product in the package is "fresh," when in fact it has been thermally processed. The Food and Drug Administration (FDA) would not object to the use of the term "fresh" in the context of a statement such as "packed from fresh tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

Dei Fratelli Fresh & Ready CHOPPED TOMATOES ONION & GARLIC (14.5 oz. cans) and Dei Fratelli Fresh & Ready CHOPPED MEXICAN TOMATOES & JALAPENOS (14.5 oz. cans)

The above products are misbranded within the meaning of Section 403 a)(1) of the Act in that their labeling is false or misleading. The statements "FRESH- PACKED" on the principal display panel and "Fresh & Ready" in the brand name of the products falsely imply that the finished products in the package are "fresh," when in fact they have been thermally processed. In addition, according to the ingredient statements, the products contain at least two preservatives. Products that have been thermally processed or that contain preservatives do not meet the definition of "fresh." As stated above, FDA does not object to the use of the term "fresh" in the context of a statement such as "packed from fresh tomatoes," provided that the tomatoes were indeed fresh as defined in 1 CFR 101.95 when they were added to the product.

The Dei Fratelli ® ***. CHOPPED MEXICAN TOMATOES & JALAPENOS product is also misbranded under section 403 (r)(1)(A) of the Act because the label bears the nutrient content claim "HEALTHY," but does not meet the requirements for the claim, as defined in 21 CFR 101.65 (d). Based on the information on the nutrition label, the CHOPPED MEXICAN TOMATOES & JALAPENOS product contains 590 mg of sodium. A "healthy" claim may be used where, among other things, the product contains no more than 360 mg of sodium.

EXHIBIT B

Furthermore, the Dei Fratelli ® *** CONCENTRATED/ITALIAN STYLE TOMATO PUREE, CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS products are misbranded under section 403(r)(1)(A) of the Act because the labels bear nutrient content claims that are not authorized by regulation for the Act or are not consistent with an authorizing regulation. The claims include "*** a great source of Vitamins A and C, and the nutrient Lycopene." In the context used on these labels, the term "great source" is considered to be an unauthorized synonym for "high." FDA has defined the nutrient content claim "high" in 21 CFR 101.54(b). "High" can be used on a food label provided the food contains 20 percent or more of the Reference Daily Intake (RDI) or Daily Reference Value (DRV) per reference amount customarily consumed.

There is no established reference value for Lycopene; therefore, the claim "*** great source of *** Lycopene" is not authorized. In addition, the Dei Fratelli ® *** CONCENTRATED/ITALIAN STYLE TOMATO PUREE does not contain 20% or more of the RDI of vitamin A and the CHOPPED MEXICAN TOMATOES & JALAPENOS does not contain 20% or more of the RDIs for Vitamin A or C.

Some of the labels for your tomato products have a "NO SALT ADDED" statement on products that are not sodium free. However, the required statement, "not a sodium free food" or "not for control of sodium in the diet" does not appear on the information panel of the labels.

We request that you take prompt action to correct these violations. Failure to achieve prompt corrections may result in enforcement action such as seizure and/or injunction being initiated by FDA without further notice.

The above violations are not meant to be an all-inclusive list of deficiencies on your labels. Other label violations can subject your food products to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by FDA.

You should also be aware that the term "fresh" in the ingredient name "FRESH TOMATOES" should not appear in the ingredient statement as part of the common or usual name of an ingredient. Ingredients must be declared by their common or usual name, as stated in section 403(I)(2) of the Act and 21 CFR 101.4(a)(1). Optional information, such as the term "fresh" is not permitted.

Also, the Dei Fratelli ® *** CHOPPED TOMATOES ONIONS & GARLIC and CHOPPED MEXICAN TOMATOES & JALAPENOS labels bear the term "All NATURAL," but according to the ingredient statements, calcium chloride and citric acid are added to the products. We have not established a regulatory definition for the term "natural," however; we discussed its use in the preamble to the food labeling final regulations (58 Federal Register 2407, January 6, 1993). FDA's policy regarding the use "natural," means that nothing artificial or synthetic has been included in, or as been added to, a food that would not normally be expected to be in the food. Therefore, the addition of calcium chloride and citric acid to these products preclude use of the term "natural" to describe this product.

Please advise us in writing within fifteen(15) working days of receipt of this letter of the specific actions you have taken to correct the violations along with copies of the revised labels. If corrective action cannot be completed within 15 days, state the reason for the delay and the time within which corrections will be completed.

Your reply should be sent to the Food and Drug Administration, 6751 Steger Drive, Cincinnati, Ohio 45237 to the attention of Evelyn D. Forney, Compliance Officer.

Sincerely,
Henry Fielden
District Director
Cincinnati District

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Oak Tree Farm Dairy, Inc. 16-Aug-01

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food & Drug Administration
New York District
158-15 Liberty Avenue
Jamaica, NY 1143

WARNING LETTER
CERTIFIED MAIL
RETURN RECEIPT REQUESTED
August 16, 2001
Ref: NYK-2001-113

Richard Classey
Vice President and General Manager
Oak Tree Farm Dairy, Inc.
544 Elwood Road
East Northport, NY 11731

Dear Mr. Classey:

On May 17 and June 5 and 7, 2001, we inspected your beverage manufacturing facility located at the above address. During the inspection, we collected a sample of your "OAKTREE REAL BREWED ICED TEA" product and labels for your "OAKTREE FRUIT PUNCH" and "OAKTREE ALL NATURAL LEMONADE" products. Our analysis of the iced tea and review of the labels found serious violations of the Federal Food, Drug, and Cosmetic Act ("the Act") and Title 21, Code of Federal Regulations, Part 101 - Food Labeling (21 CFR 101).

The "OAKTREE REAL BREWED ICED TEA" is misbranded under Section 403(i)(2) of the Act in that it contains the color additive "FD&C Red No. 40", but the certified color additive fails to be declared on the product label in the statement of ingredients by its specific name, as required (21 CFR 101.22(k)(1)). The product is also misbranded under Section 403(k) of the Act because it contains an artificial coloring that is not declared on the label.

The "OAKTREE FRUIT PUNCH" is misbranded under Section 403(k) of the Act because it contains sodium benzoate and potassium sorbate, which are not declared on the product label. A food to which a chemical preservative is added must declare the common or usual name of that ingredient and a description of its function, e.g., "preservative", as required by 21 CFR 101.226).

The above violations concern certain new labeling requirements and are not meant to be an all-inclusive list of deficiencies on your product labels. Other label violations can subject the foods to legal action. It is your responsibility to assure that all of your products are labeled in compliance with all applicable statutes enforced by the Food and Drug Administration ("FDA").

You should take prompt action to correct the violations. Failure to promptly correct these violations may result in regulatory action without further notice. These include seizure and/or injunction.

As you know, during the inspection, our investigator also reviewed the labels and formulations for your "OAKTREE ALL NATURAL LEMONADE" and "OAKTREE FRUIT PUNCH". Your lemonade label fails to declare the ingredient, citric acid, which is declared as an ingredient on the label of the lemonade concentrate used to make your lemonade. Further, your fruit punch label fails to declare the ingredients, grape juice, artificial fruit punch flavor, propylene glycol, sodium benzoate, and potassium sorbate, which are declared as ingredients on the label of the fruit punch concentrate used to make your fruit punch. Also, your fruit punch label declares the ingredients, concentrated pineapple juice, gum arabic, glycerol ester of wood resin, and blue 1.

EXHIBIT C

However, these ingredients are not found in the fruit punch concentrate used to make your fruit punch and are not listed as ingredients in your fruit punch formulation. The investigator discussed these labeling discrepancies with you at the conclusion of the inspection.

The term "all natural" on the "OAKTREE ALL NATURAL LEMONADE" label is inappropriate because the product contains potassium sorbate. Although FDA has not established a regulatory definition for "natural," we discussed its use in the preamble to the food labeling final regulations (58 Federal Register 2407, January 6 1993, copy enclosed). FDA's policy regarding the use of "natural," means nothing artificial or synthetic has been included in, or has been added to, a food that would not normally be expected to be in the food. The same comment applies to use of the terms "100 % NATURAL" and "ALL NATURAL" on the "OAKTREE REAL BREWED ICED TEA" label because it contains citric acid.

Further, the declaration of potassium sorbate in the ingredient statement on the "OAKTREE ALL NATURAL LEMONADE" label must be followed by a description of its function, e.g., "preservative", as required by 21 CFR 101.22(j).

You should notify this office in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. If corrective action cannot be completed within 15 days, state the reasons for the delay and the time within which the corrections will be completed.

Your reply should be directed to Bruce A. Goldwitz, Compliance Officer, Food and Drug Administration, 158-15 Liberty Avenue, Jamaica, New York 11433. If you have any questions concerning the violations noted, please contact Mr. Goldwitz at (718) 340-7000 ext. 5582.

Sincerely,

/s/

Robert L. Hart

Acting District Director

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